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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,653	09/30/2003	Marc E. Feinberg	ETH5092	4786

27777 7590 01/05/2007
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EXAMINER

POUS, NATALIE R

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,653	FEINBERG, MARC E.	
	Examiner	Art Unit	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6,8,10,12,14,16 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,6,8,10,12,14,16 and 18-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/16/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of species 2 in the reply filed on 10/23/06 is acknowledged.

Response to Arguments

Regarding Hasson

Applicant's arguments with respect to claims 1, 2 and 1-21 have been considered but are moot in view of the new ground(s) of rejection.

Regarding Fogarty

Applicant's arguments with respect to claims 1, 5, 6, 12, 14, 16 and 18 have been considered but are moot in view of the new ground(s) of rejection.

Regarding the 103 rejection

Applicant's arguments with respect to claims 8 and 10 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 5, 6, 10, 14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Benetti et al. (US 6050266).

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Regarding Claim 1, Benetti teaches a tissue approximation device comprising two elongate arms (3), an attachment means (16) to secure the elongate arms to each other at one or more locations, adhesive pads (4) on at least a portion of the elongate arms to anchor the tissue approximation device to the tissue (fig. 2a), and a locking means (18) to lock the elongate arms in place relative to each other, wherein (i) the adhesive pads are spaced apart from the one or more locations of the attachment means (16) in the direction of the elongate arms, and (ii) the tissue approximation device has an open (fig. 2b) and a closed position (fig. 2a), and when in the closed position, the adhesive pads are parallel and non-contiguous to each other (fig. 2a).

Regarding Claim 5, Benetti teaches the tissue approximation device of claim 1, wherein the elongate arms (3) form a pair of forceps, the attachment means (16) is a yoke on the forceps, and the locking means (18) is a ratchet mechanism on the forceps (Column 9, proximate lines 30-32).

Regarding Claim 6, Benetti teaches the tissue approximation device of claim 5, wherein the distance between the elongate arms is adjustable by means of a ratchet mechanism (18).

Regarding Claim 10, Benetti teaches the tissue approximation device of claim 5, wherein the adhesive pad having first adhering surface (4) and a second surface having a ball (5) that communicates with a socket on the distal end of the arm.

Regarding Claim 14, Benetti teaches the tissue approximation device of claim 5, wherein the adhesive pad having first adhering surface (4) and a second surface having

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a male protruding mechanism (19) that communicates with a female receiving mechanism (17) on the distal end of each of the elongate arms (3).

Regarding Claim 16, Benetti teaches the tissue approximation device of claim 5, wherein the distal end of the elongate arms has a passageway (17) therein such that the adhesive pad (19) communicates with said passageway (17).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benetti in view of Fogarty (US 4821719). Benetti teaches all limitations of preceding dependent claims 1 and 5, but fails to teach wherein the adhesive pad has a first surface and a second surface having a female receiving mechanism that communicates with a male protrusion on the distal end of each of the elongate arms, or

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wherein the adhesive pad has a passageway therein, such that the distal end of each of the elongate arms is within said passageway.

Fogarty teaches a device for tissue approximation wherein the adhesive pad has a first surface (30a) and a second surface (55) having a female receiving mechanism that communicates with a male protrusion (52) on the distal end of each of the elongate arms (fig. 5), or wherein the adhesive pad has a passageway therein (55), such that the distal end of each of the elongate arms (52) is within said passageway (fig. 5), in order to provide adhesive pads that are releasably secured in place and may be readily replaced. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Benetti with the securing mechanisms of Fogarty in order to provide adhesive pads that are releasably secured in place and may be readily replaced.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Benetti in view of Agnone (US 3754331). Benetti teaches all limitations of preceding dependent claims 1 and 5, but fails to disclose wherein the elongate member and pad form a ball and socket connection. Agnone teaches forceps wherein the distal pads connect to the elongate members by means of a ball and socket joint in order to allow the pads to move independently of the elongate arms and gain a better grip on the tissue. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Benetti with a ball and socket joint as taught by Agnone in order to allow the pads to move independently of the elongate arms and gain a better grip on the tissue.

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Claims 1 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huttner (US 6042599) in view of Hasson (US 3926193)

Huttner teaches a device and method of closing a wound comprising the steps of: providing a tissue approximation device (10) comprising two elongate arms (17, 18), an attachment means (25) at one or more locations to secure the arms to each other, pads (43, 44) on the ends of the elongate arms to anchor the tissue approximation device to the skin (fig. 1), and a locking means (46) to lock the elongate arms in place relative to each other, wherein (i) the pads are spaced apart from the one or more locations of the attachment means (46) in the direction of the elongate arms, and (ii) the tissue approximation device has an open (fig. 1) and a closed position (fig. 2), and when in the closed position, the pads are parallel and non-contiguous to each other (fig. 2); positioning the adhesive pads to the skin on opposed sides of a wound (12); approximating the wound closure by actuating the tissue approximation device in a direction to move the pads towards each other in a common plane that is generally parallel to the skin tissue (fig. 2); engaging the locking means (45) to assure that the edges surfaces of the wound do not move; applying a topical skin closure adhesive to the wound (Column 3, proximate lines 35-36) and removing the pads from the skin tissue (Column 3, proximate lines 40-43).

where the attachment means and the locking means (46) are the same.

wherein the pads (43, 444) are located on at least a portion of each of the elongate arms (17, 18).

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Huttner fails to teach wherein the pads comprise an adhesive. Hasson teaches a tissue approximation device comprising an adhesive material (12) in order to effectively secure the tissue approximation device to the skin during use. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Huttner with an adhesive as taught by Hasson in order to effectively secure the tissue approximation device to the skin during use.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-

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6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
12/11/06


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
12/22/06